IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

SERAVEA MORIES,	:	
	:	**Case No. 2:19-CV-05671**
Plaintiff,	:	
	:	**CHIEF JUDGE ALGENON L. MARBLEY**
v.	:	
	:	**Magistrate Judge Kimberly A. Jolson**
BOSTON SCIENTIFIC CORPORATION,	:	
	:	
and	:	
	:	
JOHN DOES MANUFACTURERS, SUPPLIERS, and/or RETAILERS #1-3	:	
	:	
Defendants.		

OPINION & ORDER

This matter is before the Court on Defendant Boston Scientific Motion to Dismiss. (ECF Nos. 5, 23). Defendant moves this Court to dismiss Plaintiff's First Amended Complaint, arguing that Plaintiff's claims are preempted and that she fails to state a claim upon which relief may be granted. Plaintiff responded, arguing that preemption is improper because she has stated a valid, parallel claim under Ohio and federal law. (ECF No. 26). Due to the suspension of in-court proceedings as a result of the COVID-19 pandemic, the Court will resolve this Motion on the briefs and without oral argument. For the reasons set forth below, the Court **GRANTS IN PART** and **DENIES IN PART** Defendant's Motion to Dismiss. (ECF No. 23).

I. BACKGROUND

Plaintiff Seravea Mories initiated this civil action on December 31, 2019, alleging that she was injured by a medical device Spinal Cord Stimulator ("SCS 1132") made by Defendant Boston Scientific. (ECF No. 2). In her First Amended Complaint, Plaintiff alleges that the device was

defective and had to be removed due to Defendant's failure to satisfy its obligations under the Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments of 1976, 21 U.S.C. § 301 *et seq.* ("MDA"). (ECF No. 15). Plaintiff initially filed this action in the Franklin County Court of Common Pleas, and it was removed to this Court. (ECF No. 1).

Around November 30, 2017, Plaintiff reports that a Boston Scientific SCS 1132 was surgically implanted into Plaintiff's back by Dr. Jimmy Henry. (ECF No. 15 ¶ 9). The stimulator is used to alleviate chronic pain by stopping pain signals before they can reach the brain. (ECF No. 15 ¶ 11, Ex. 1).

For six months after her November 2017 surgery, Plaintiff's SCS 1132 worked as anticipated. (ECF No. 15 ¶ 17). Six months later, however, Plaintiff began experiencing painful, sporadic shocks at the implant site. (ECF No. 15. ¶ 18). In an attempt to minimize the frequency of the shocks, Plaintiff occasionally turned the SCS 1132 off. (*Id.* at ¶ 19). But the shocks continued, even when the SCS 1132 was turned off. (*Id.*) Plaintiff sought additional medical attention. Her doctor, Dr. Amy Murnen, ultimately recommended the device's removal. (*Id.* at ¶ 22).

The SCS 1132, Plaintiff proffers, has been associated with causing unintended, sporadic painful shocks, malfunctions, and battery-related issues. (*Id.* at ¶ 24). Plaintiff claims Defendant has acknowledged that the SCS 1132 is susceptible to device failure and operational malfunctions. (*Id.* at ¶ 32). Plaintiff contends that as a direct and proximate result of the SCS 1132's defects, she was forced to endure ongoing medical treatment, has experienced mental and physical pain, lost past and future income, has a decreased earning capacity, has lost the enjoyment and pleasures of life, and anticipates additional negative consequences. (*Id.* at ¶ 49).

Plaintiff filed this lawsuit, raising counts one through six against Boston Scientific and count seven against unnamed manufacturers, suppliers, and retailers. Only counts one through six are relevant to the resolution of Defendant's motion to dismiss. Plaintiff's claims against Defendant Boston Scientific are as follows:

1) **Count One:** Design and Manufacturing Defect
2) **Count Two:** Failure to Warn
3) **Count Three:** Negligent Handling
4) **Count Four:** Breach of Express and Implied Warranties
5) **Count Five:** Negligent and Fraudulent Misrepresentation
6) **Count Six:** Failure to Report

This Court reviews each of these claims in turn.

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(6) provides for the dismissal of a complaint for a failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). To survive a motion to dismiss, "the plaintiff must allege facts that, if accepted as true, are sufficient to raise a right to relief above the speculative level and to state a claim to relief that is plausible on its face." *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 609 (6th Cir. 2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007)) (internal quotations omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)). And although the court "must accept all well-pleaded factual allegations in the complaint as true," the court "need not accept as true a legal conclusion couched as a factual allegation." *Id.* (quoting *Twombly*, 550 U.S. at 555) (internal quotations omitted).

Whether a claim is subject to federal preemption under the Medical Device Amendments Act of 1976 ("MDA") is a question of law and therefore can be resolved through a motion to dismiss under Fed. R. Civ. P. 12(b)(6). *See, e.g.*, *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 107 (2d Cir. 2006), *aff'd*, 552 U.S. 312 (2008).

II. LAW & ANALYSIS

Defendant moved to dismiss Plaintiff's First Amended Complaint as preempted under the MDA and for a failure to state a claim upon which relief can be granted. This Court reviews these claims below.

A. Preemption Under The Medical Device Amendments

First, Defendant contends that Plaintiff's claims are expressly preempted under the MDA. The spinal-cord stimulator at issue here, like all medical devices in the nation, is regulated by the Food and Drug Administration ("FDA"), which draws its regulatory power from the MDA. Congress enacted the MDA to regulate medical devices intended for human use. The MDA divides its regulatory scope into three "classes," with each class receiving different FDA scrutiny levels. Devices that "present[] a potential unreasonable risk of illness or injury" are called Class III devices. 21 U.S.C. § 360c.

Class III devices are subject to extensive regulatory scrutiny, in a process known as "premarket approval" or "PMA." During the premarket approval review, a manufacturer must provide the FDA with a "reasonable assurance" that the device is safe and fit for human use. 21 U.S.C. § 360e(d)(2). In addition, the FDA's PMA review process includes weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). After this review concludes, the FDA grants or denies regulatory approval for the reviewed medical device. 21 U.S.C. § 360e(d).

The medical device at issue here was approved through the PMA process. 69 Fed. Reg. 58,446-48 (Sep. 30, 2004) (listing the original April 27, 2004 PMA approval for a line of spinal cord stimulators, including the SCS 1132). Defendant represents that the specific model—the SCS 1132—was granted supplemental premarket approval on December 21, 2012. (ECF No. 6 at 6).

Most important for review of Defendant's preemption defense is the MDA's express preemption clause, contained in 21 U.S.C. § 360k(a). The preemption clause reads as follows:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The exception contained in subsection (b) allows the regulator to exempt some state and local statutory requirements from preemption. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1992) (explaining that this provision "simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions").

The United States Supreme Court has had a handful of opportunities to interpret the MDA's preemption provision. Of substantial relevance here is *Riegel v. Medtronic Inc.*, 552 U.S. 312 (2008). In *Riegel*, the Court reviewed whether a device that had undergone the PMA review process, per § 360k, was preempted. Broadly, the Court held that the FDA's PMA process for Class III medical devices imposes device-specific federal requirements that has a preemptive effect under the MDA. Preemption was proper when the state law imposed safety requirements exceeding the ceiling that the federal requirements established. *Id.* at 325 ("State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.").

FDA regulations interpret the MDA preemption provision to preempt state requirements that are "different from, or in addition to, any requirement applicable under" federal law, when the state law "relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). That is, the MDA does not permit a state to impose different or additional regulations on Class III medical devices. A shorthand for this MDA preemption rule is "mirror-and-ceiling." To avoid preemption, a state-law claim must emerge from a state law that is a "mirror" to the MDA—the state law cannot impose any different requirements and must accurately reflect federal requirements. In addition, the MDA is the "ceiling"—no state law can impose requirements that exceed what the federal statute provides.

It bears repeating that the MDA's preemptive effect is not absolute. The federal law "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Riegel*, 552 U.S. at 312. In such a case, the state claims are not preempted because the state duties run "parallel, rather than add to, federal requirements." *Id.* at 321-22.

1. Two-Part Riegel Test

With respect to Class III medical devices, like the SCS 1132 at issue here, the Supreme Court in *Riegel* established a two-part test to determine if the MDA expressly preempts a state-law claim.

First, courts ask whether the federal government has established requirements applicable to the medical device in question. All PMA-approved medical devices, including Class III medical devices, automatically fulfill this first step. *See Riegel*, 552 U.S. at 332 ("Premarket approval . . . imposes 'requirements' under the MDA . . . . ").

Second, any state-law requirement imposed on an FDA-regulated medical device that is "different from, or in addition to," FDA requirements is preempted. *Riegel*, 552 U.S. at 317

(quoting 21 U.S.C. § 360k(a)(1)). A claim premised upon a state law will be preempted where "judges and juries [would be required] to second-guess the balancing of benefits and risks of a specific device to their intended patient population—the central role of FDA." *Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004) (quoting another source). Conversely, if the state law provides a damages remedy for claims premised on a violation of the FDA regulations themselves, then the state duties parallel, rather than add to or deviate from, federal requirements. *Lohr*, 518 U.S. at 495.

2. Riegel's Progeny

Post-*Riegel*, there has been considerable confusion about and conflict among district courts of what constitutes a parallel state claim. *Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 827 (W.D. Ky. 2014) ("[D]ifferent circuit courts have adopted different approaches as to the required pleading specificity in the context of MDA preemption."). A brief review of two seminal MDA preemption cases within this district is illustrative of varying judicial approaches to this question.

Endorsing a relaxed pleading standard is *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901 (S.D. Ohio 2012). In *Hawkins*, like here, a patient sued a medical device manufacturer, alleging that the medical device that was surgically implanted into his back was defective and that the device ultimately had to be replaced due to the manufacturer's failure to satisfy its duties under the MDA. The manufacturer moved to dismiss. In a partial denial of the motion, the court found that the preemption challenge to the plaintiff's products-liability claims could not be resolved at the motion to dismiss stage. Plaintiff relies heavily on the *Hawkins* opinion, with her filings, at times, tracking the *Hawkins* allegations claim-for-claim and word-for-word.

Four years later, this district had another occasion to review the MDA preemption question—but this time, the court backed a much stricter pleading standard. *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994 (S.D. Ohio 2016) ("[T]his Court rejects the reduced pleading standard for products liability cases involving FDA Class III medical devices . . . .").

This lower-court confusion notwithstanding, these cases are not irreconcilable. *See White v. Stryker Corp.*, 818 F.Supp.2d 1032, 1039 (W.D.Ky. 2011) ("These cases reveal the different approaches to resolving MDA preemption issues, though one can overstate the differences. No doubt, specific factual and procedural differences among the cases partially explain the different results.").

With this landscape established, this Court proceeds to review two questions. First, whether federal law preempts Plaintiff's claims against Defendant. Second, whether the Amended Complaint pleads a plausible parallel claim for relief as required by federal pleading standards under Rule 8.

Defendant moved to dismiss Plaintiff's First Amended Complaint as preempted and for a failure to state a claim upon which relief can be granted. Defendant advances several arguments. This Court will address each of these arguments, in turn, below.

B. Judicial Notice

As a preliminary matter, this Court grants Defendant's request to take judicial notice of public documents, including those filed with the FDA, cited in their various motions to dismiss. (ECF No. 23). In ruling on a motion to dismiss, the Court "may consider materials in addition to the complaint if such materials are public records or are otherwise appropriate for the taking of judicial notice." *New England Health Care Employees Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003). A court may consider public records of which a court may take

judicial notice without converting a motion to dismiss into a motion for summary judgment. *Weiner v. Klais & Co.*, 108 F.3d 86, 89 (6th Cir. 1997); *see Aaron*, 209 F. Supp. 3d at 1014 (taking judicial notice of FDA records indicating that the device had received premarket approval).

C. Whether The MDA Preempts Plaintiff's Tort-Related Claims

Defendant Boston Scientific first moves to dismiss Plaintiff's Amended Complaint under Federal Rule of Civil Procedure 12(b)(6), arguing that the Plaintiff fails to plead a parallel claim under Ohio tort law and is thus preempted by the MDA. The parties agree that § 360k expresses congressional intent to preempt state tort-law requirements. They disagree about the scope of that preemptive impact. Here, the federal government has established requirements "applicable to" the SCS 1132, which satisfies the first inquiry of the two-part *Riegel* test. The second prong requires a more searching review, which will be the subject of this Court's discussion below.

Broadly, Defendant's argument falls into four buckets: (1) Plaintiff's claims allege defects in a medical device's design, construction, manufacturing methods, testing, and labeling, all of which were specifically approved by the FDA pursuant to the agency's most rigorous Premarket Approval process; (2) Plaintiff fails to assert "parallel" claims, which, if successfully pled, would survive express preemption; (3) Plaintiff does not allege any cognizable link between the device at issue and her alleged injuries; and (4) at any rate, Plaintiff's claims would require an Ohio jury to contradict the FDA's findings, which necessitates preemption as well.

1. Design and Manufacturing Defects (Count One)

Plaintiff's design and manufacturing claim asserted in Count One of the First Amended Complaint arises from Ohio Revised Code §§ 2307.74[1] and 2307.75,[2] and under the MDA[3] and its related regulations.[4] In particular, Plaintiff argues that the SCS 1132 contained a design or

[1] Section 2307.74, which provides that "[a] product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards."

[2] Section 2307.75, which provides that "a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation."

[3] Count One cites the MDA, including, but not limited to the following sections of Title 21 of the U.S. Code:

- Section 351, which discuses when a medical device is adulterated. 21 U.S.C.A. § 351.
- Section 360(d), by which this Court assumes Plaintiff means § 360d, which sets forth the performance standards for certain medical devices. 21 U.S.C.A. § 360d.
- Section 360(e), by which this Court assumes Plaintiff means § 360e, which sets forth the rules regarding the PMA process. 21 U.S.C.A. § 360e.
- Section 360(h), by which this Court assumes Plaintiff means § 360h, which explains the notification duties for manufacturers and others in the medical community to notify relevant individuals of a device intended for human use that poses an unreasonable risk of substantial harm to public health.

[4] Plaintiff's Count One cites the following sections of Title 21 of the Code of Federal Regulations:

- Section 820.01, by which this Court assumes Plaintiff means § 820.1, which sets forth the scope of the FDA's quality system regulation.
- Section 820.5, which requires medical device manufacturers to establish and maintain a quality system.
- Section 820.20, which provides for management responsibility.
- Section 820.22, which requires quality audits.
- Section 820.25, which sets qualification requirements for manufacturer personnel.
- Section 820.30, which provides that manufacturers must "establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met."
- Section 820.70, which sets forth rules regarding production and process controls.
- Section 820.72, which sets forth rules regarding inspection, measuring, and test equipment.
- Section 820.75, which sets forth rules regarding process validation.
- Section 820.80, which requires manufacturers to "establish and maintain procedures for acceptance activities ... includ[ing] inspections, tests, or other verification activities.

manufacturing defect, was adulterated, failed to comply with the premarket approval specifications, and was unsafe and non-conforming, resulting in her injuries. The SCS 1132, Plaintiff proffers, was not intended, designed, or manufactured to produce sporadic, unexpected, painful shocks post-implantation. Ultimately, she claims that these defects substantially caused her injuries.

To support its Motion to Dismiss, Defendant retorts that Plaintiff cannot state a parallel claim because her Amended Complaint only sets forth bare legal conclusions, without the requisite factual support about how the medical device operated in any one of the federal regulations she identifies. In addition, it claims Count One is preempted because Plaintiff is *not* alleging that Defendant failed to meet the FDA requirements—which, if true, would survive preemption. Rather, Defendant claims that Plaintiff's common-law allegation arises from a state law that would impose additional requirements on Defendant to design and manufacture an even safer medical device, in violation of the regulatory ceiling the MDA establishes.

This Court finds that Plaintiff's design and manufacturing defect claim survives Defendant's Motion to Dismiss. To state a parallel claim and avoid preemption under § 360k(a), a plaintiff must identify state law that parallels federal regulations. As discussed above, an action based on a state law will fail where the state law does not mirror federal requirements or imposes requirements exceeding the MDA statutory ceiling. A plaintiff must bolster her legal claims with

- Section 820.86, which requires manufacturers to identify the "conformance or nonconformance of product with acceptance criteria ... throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed."
- Section 820.90, which requires manufacturers to "establish and maintain procedures to control product that does not conform to specified requirements."
- Section 820.100, which requires manufacturers to "establish and maintain procedures for implementing corrective and preventive action" to address nonconforming product.

factual evidence about how the medical device at issue violated the federal regulation. *See Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) ("To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated.") (quoting another source).

Plaintiff's First Amended Complaint alleges that Defendant's design and manufacture of the SCS 1132 failed to comply with PMA specifications and was generally non-conforming. Plaintiff's state-law strict liability design- and manufacture-defect claim is predicated on a failure to meet the FDA's requirements. *See, e.g.*, *Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir. 2012) ("To the extent a plaintiff can show that the FDA-approved processes and procedures were not followed, and that the injury was caused by this deviation, the plaintiff's claim will be parallel."). If, following the completion of discovery, Plaintiff cannot sustain a claim under state requirements that parallel federal requirements, Defendant would be free to file a motion for summary judgment. Thus, to the extent—and only to the extent—Plaintiff's claim that the device was defectively designed or manufactured because it did not comply with the FDA-approved specifications, this Court finds that the Plaintiff has successfully alleged a parallel claim sufficient to survive preemption under § 360k(a).

In reaching this conclusion, this Court finds the *Hawkins* standard persuasive. That court said: "[T]he preemption issue here must be decided on the pleadings, and the complaint has not defined the precise contours of the plaintiff's theory of recovery, the Court can not engage in a detailed comparison of the specific state and federal requirements at issue. However, because it is clear that the allegations . . . include claims that [Defendant] has . . . violated FDA regulations, these claims can be maintained without being pre-empted by § 360k." *Hawkins*, 909 F. Supp. 2d at 905 (internal quotation marks omitted). So too here.

The Court **DENIES** Defendant's Motion to Dismiss Count One.

2. Failure To Warn (Count Two)

Plaintiff's failure-to-warn claim set forth in Count Two of the First Amended Complaint emerges from Ohio Revised Code § 2307.76[5] and the MDA[6] and its subsequent regulations.[7] In her count, Plaintiff alleges that the Defendant failed to warn her and her physician of the medical device's known defects. This failure-to-warn, she alleges, constituted a flagrant disregard of the safety of persons, like her, who might be harmed by the SCS 1132.

The FDA has an ongoing post-market surveillance duty to monitor the safety and efficacy of medical devices approved for public consumption. Reports of individuals experiencing negative or unexpected side effects from a medical device sometimes leads the device manufacturer to submit an Adverse Event Reports ("AERS") with the FDA, accessible in an online database for all approved medical devices. Healthcare professionals and consumers can also report these adverse outcomes to the medical device's manufacturers. While the decision to report an adverse event is voluntary, if a manufacturer receives an adverse event report from a consumer or other interested individual, it must send that report to the FDA.

---

[5] Section 2307.76, which sets forth when a product is defective due to inadequate warning or instruction.

[6] Count Two cites the following sections of the Title 21 of the U.S. Code:

- Section 360(h), by which this Court assumes Plaintiff means § 360h, which explains the notification duties for manufacturers and others in the medical community to notify relevant individuals of a device intended for human use that poses an unreasonable risk of substantial harm to public health.
- Section 360(i). by which this Court assumes Plaintiff means § 360i, which outlines the requirements for manufacturers of medical devices to establish and maintain records and reports.

[7] Count Two cites the following federal regulations:

- 21 C.F.R. §§ 803.50 and 803.52, which describe reporting requirements.
- 21 C.F.R. § 814.82, which describes allowable post-PMA requirements.

Defendant argues that Plaintiff's failure to warn claim is preempted for two reasons. First, the Defendant says that the AERS—which Plaintiff cites in her exhibits as evidence of Defendant's wrongdoing—indicates that Defendant is complying with its obligation to report adverse events to the FDA. Second, the Defendant claims that Plaintiff fails to identify any parallel state-law obligation that is equivalent to the FDA requirement to report adverse events. It cites *Aaron v. Medtronic*, where the Southern District of Ohio reasoned that "the requirements imposed by Ohio state law and the FDA's adverse-event report rule are not parallel." *See Aaron*, 209 F. Supp. 3d at 1006 (quoting *Pinsonneault v. St. Judge Med., Inc.*, 953 F.Supp.2d 1006, 1016 (D. Minn. 2013).

Plaintiff's failure-to-warn claim is analogous to a failure-to-warn claim that the Sixth Circuit reviewed in *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000). There, the plaintiff alleged broadly: "If, following the completion of discovery, Plaintiff cannot sustain a claim under state requirements that parallel federal requirements, Defendant would be free to file a motion for summary judgment." *Id.* at 236.

The Sixth Circuit, finding it "difficult to determine . . . the underlying basis of plaintiffs' claim," reasoned that the failure-to-warn allegation could be read multiple ways. First, plaintiff's allegation could be read as asserting that the warnings found in the label and literature approved by the FDA were inadequate under Ohio law. Second, the statement could also be read to assert a distinct claim that the defendant acquired information subsequent to the FDA approval that the medical device and before implantation of the device that would lead a reasonable manufacturer to warn patients and the medical community. *Id.*

This Court arrives at a similar rationale. Plaintiff's failure-to-warn allegation is ambiguous and could be read also variously; one interpretation would subject the allegation to preemption, and the other would not. The difference between the preempted and non-preempted failure-to-

warn claim is temporal—*i.e.*, before or after the FDA approved the warnings and literature associated with the SCS 1132. To the extent that Plaintiff alleges Defendant's FDA-approved warnings were themselves inadequate under state law, such claims are preempted. *See Martin*, 105 F.3d at 1100 ("To allow a state cause of action for inadequate warnings would impose different requirements or requirements in addition to those required by federal regulations."). Such a claim would be improper because it would require a court to second-guess the FDA's determination that the marketing literature was appropriate and adequate.

But, like in *Kemp*, there is another way to interpret Plaintiff's failure-to-warn claim such that it avoids preemption. Count Two could be read as alleging a breach of Defendant's duty under state law to warn of potential defects, based on information Defendant obtained *after* the FDA's approval of the medical device. *Kemp*, 231 F.3d at 237. In other words, if Plaintiff is alleging that Defendant failed-to-warn of design or manufacture defects after the FDA approved of the warnings and literature, then she is not asking for a court to disagree with any federal determination. *Cf. Aaron*, 209 F. Supp.3d at 1006.

Analogous to Count One, Count Two has not defined "the precise contours of [the plaintiff's] theory of recovery, and the Court cannot engage in a detailed comparison of the specific state and federal requirements at issue. It is clear from the allegations, however, that Plaintiff's claim is premised on the theory that Defendant violated federal law." *See Riegel*, 552 U.S. at 330 (quoting *Kemp*, 231 F.3d at 237). This Court, therefore, **DENIES** Defendant's motion as to Count Two. *See Riegel*, 552 U.S. at 330.

3. Negligent Handling (Count Three)

In Count Three, Plaintiff alleges that the Defendant failed to establish or maintain adequate distribution, installation, handling, and inspection instructions or procedures in violation of the

MDA and 21 C.F.R. §§ 820.140, 820.150, 820.160, and 820.170. Plaintiff does not allege any cause of action under Ohio law, and the MDA also provides no such private cause of action. The First Amended Complaint accordingly cannot support a parallel claim under state law. *Bailey v. Johnson*, 48 F.3d 965, 966 (6th Cir. 1995) ("Because we conclude that Congress did not intend to create a private cause of action when it enacted the FDCA, we reverse."). This Court **GRANTS** Defendant's Motion to Dismiss as to Count Three.

4. Express and Implied Warranties (Count Four)

In Count Four, Plaintiff alleges that the Defendant breached express and implied warranties that the SCS 1132 was safe and effective and would mask pain impulses as an aid in the management of chronic intractable pain. Specifically, Plaintiff contends that Defendant, through published materials, misrepresented the longevity, safety, and utility of the medical device. The breach of these express and implied warranties, she charges, is the direct and proximate cause for her physical injuries and ongoing medical expenses.

The Defendant argues that the MDA preempts Count Three's express and implied warranty claims. The FDA's grant of PMA status to the SCS 1132 suffices as evidence that the medical device was not defectively designed or dangerous, Defendant argues. As a result, any jury finding to the contrary would contravene the federal premarket approval determination that the SCS 1132 was a safe and effective medical device, Defendant claims. *See Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *10 (N.D.Ga. Aug. 19, 2011) ("In order to prove that Medtronic breached this warranty, Plaintiffs would need to show that the ICD was not safe and reliable, a finding that would directly conflict with the FDA's premarket approval of the device as reasonably safe and effective.") (citing 21 U.S.C. § 360e(d)).

Defendant further takes issue with Plaintiff's characterization of the PMA process. It emphasizes that no medical device is risk-free. Rather, the FDA is challenged with balancing the benefits of a medical device with the harm of malfunction, but this does not guarantee a risk-free product. *See Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008) ("As the Supreme Court aptly recognized [in *Riegel*], the premarket approval process is ultimately a cost-benefit analysis in which the potential health benefits are weighed against the potential risks.") (citing *Riegel*, 552 U.S. 312).

Neither party distinguishes between the breach of an express and implied warranty. There are, however, important differences. For a thorough explanation of this Court's holding, it is important to highlight the legal distinctions between these claims. This Court does so below.

a. Express Warranty

Unlike implied warranties, express warranties arise through private agreements made by parties and do not emerge from state law. *Bentzley v. Medtronic, Inc.*, 827 F.Supp.2d 443, 454 (E.D.Pa. 2011). The consequence is that express-warranty representations arise from the warrantor—not from state law. In the medical-device context, express warranties establish a voluntary, contractual relationship entered into by the manufacturer with a plaintiff.

This Court leaves a narrow window for Plaintiff's express-warranty claim to continue. The claim is not preempted, but only insofar as Count Four identifies specific representations by Defendant—on which Plaintiff relied—that exceeded the scope of the FDA-approved statements. *See Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 285 (E.D.N.Y. 2009). Any claim for breach of express warranty premised upon or intertwined with an FDA-approved publication, however, must be preempted.

The *Hawkins* court reviewed a similar claim. It found: "Because an Ohio claim for breach of express warranty does not require a finding that the manufacturer's representations are untrue, the Court finds that a successful lawsuit would not 'threaten the federal PMA process requirements.'" *Hawkins*, 909 F. Supp. 2d at 911 (quoting *Gomez v. St. Jude Med. Daig Div.*, 442 F.3d 919, 932 (2006)); *see also Wagner v. Roche Lab.*, 85 Ohio St.3d 457, 709 N.E.2d 162, 166 (1999) (listing the elements of a breach of express warranty claim under Ohio law).

This Court finds that Plaintiff's express-warranty claim survives preemption at the motion-to-dismiss stage, as the allegations indicate that her claim is premised upon the theory that Defendant violated federal law. Her claim survives to the extent she seeks to recover based on breached warranties that the Defendant falsely made, independent of the FDA-approved warning.

b. Implied Warranty

Implied warranties arise by operation of state law, unlike express warranties explored above. Yet, Plaintiff's First Amended Complaint and related documents lack an articulation of how any implied warranty allegedly made by the Defendant would be enforceable under Ohio law in a parallel fashion so as to avoid preemption. *Cf. Hawkins*, 909 F. Supp. 2d at 911. This makes it difficult for this Court to assess whether a breach of implied warranty claim would impose non-parallel state law requirements—in which case, it would be preempted. In addition, Count Four does not identify the federal violations that purportedly correspond to this claim.

These shortcomings notwithstanding, Plaintiff's implied warranty claim also survives Defendant's Motion to Dismiss. Plaintiff's Count Four incorporates the rest of her Amended Complaint, which identifies federal violations, evidencing that her claim is premised upon a violation of federal law. Ultimately, of course, Plaintiff will have to demonstrate causality between the alleged non-compliance with the FDA requirements and the breach of the implied warranty.

Accordingly, Defendant's Motion to Dismiss Plaintiff's claim of breach of express and implied warranties as preempted § 360k(a) is **DENIED**.

5. Negligent and Fraudulent Misrepresentation (Count Five)

Plaintiff's negligent- and fraudulent-misrepresentation claim in Count Five alleges that she was harmed by relying on Defendant's false statements that the SCS 1132 was safe and effective despite knowledge to the contrary and in violation of federal law. Specifically, she characterizes the following representations as negligent and fraudulent: (1) that the SCS 1132 was used as an aid in the management of chronic, intractable pain, which would mask pain impulses, (2) the SCS 1132 reduced pain by at least 50%, and (3) has been proven safe and effective. (ECF No. 15).

Defendant challenges Count Five by arguing that Plaintiff misunderstands the FDA approval process—the PMA review does not guarantee universal, patient-by-patient efficacy. And the FDA's approval of the device's labeling and advertising evinces the SCS 1132's relative safety, Defendant says. More generally, to the extent Plaintiff's misrepresentation sounds in fraud, Defendant argues it fails to be plead with the requisite level of particularity needed.

Plaintiff's misrepresentation claim is subject to the heightened pleading standard in Federal Rule of Civil Procedure 9, which states: "Fraud or Mistake; Conditions of Mind. In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

The Sixth Circuit has held that Rule 9(b) requires a claim of fraud to "allege the time, place, and content of the alleged misrepresentations on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Sanderson v.*

HCA–The Healthcare Co. et al., 447 F.3d 873, 877 (6th Cir. 2006) (quoting *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 563 (6th Cir. 2003)).

Plaintiff's fraud claim lacks this particularity. Absent from Plaintiff's allegations are the time, place, and content of the alleged misrepresentation, the nature of the fraudulent scheme, the Defendant's fraudulent intent, and the causality between the fraud and her a subsequent injury. As for proof, Plaintiff points to Defendant's SCS 1132 marketing materials, an e-mail Plaintiff's doctor authored reporting that Plaintiff had begun experiencing painful shocks, and the earlier-mentioned adverse event reports. These are not sufficient facts to substantiate an alleged violation, at least not without further specification. Even the *Hawkins* court, which embraced a relaxed pleading standard in a parallel context, rejected the plaintiff's negligent and fraudulent misrepresentation allegations. *Hawkins*, 909 F. Supp. at 911 (reasoning representations made about non-investigational devices are preempted) (citing *Martin v. Telectronics Pacing Sys.*, 105 F.3d 1090, 1100 (6th Cir. 1997). Accordingly, Defendant's motion to dismiss Plaintiff's negligent and fraudulent misrepresentation claim is **GRANTED**.

D. Failure to Report (Count Six)

In Count Six, Plaintiff alleges that Defendant failed to report adequately and accurately a malfunction associated with SCS 1132 and generally failed to maintain a system to identify and respond to complaints of defective products.

Plaintiff relies on *Hughes v. Boston Scientific Corp.* for support. 631 F.3d 762. But that case is distinguishable. In *Hughes*, the plaintiff alleged a failure to make reports to the FDA in violation of federal reporting requirements and state law. *Id.* at 22. Here, Plaintiff has not identified any Ohio state-law requirement to make reports to the FDA, thus critically weakening her parallel-claim allegation. In addition, the *Hawkins* court rejected a similar failure-to-report claim. That

court so held because the MDA provides no private cause of action, and the *Hawkins* plaintiff failed to identify a failure-to-report cause of action under Ohio law. *Hawkins*, 909 F. Supp. 2d at 911. Even if such a state cause of action had been identified, the claim would still be preempted under the MDA. The Supreme Court has held that a "state-law-fraud-on-the-FDA claim[] [would] conflict with, and [is] therefore impliedly pre-empted by federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). Claim Six, therefore, fails to state a claim upon which relief can be granted and, and Defendant's Motion to dismiss Count Six is hereby **GRANTED.**

E. Pleading Sufficiency

Second, the Defendant's final argument in support of its Motion to Dismiss is that Plaintiff failed to plead sufficient facts to state a claim for relief that is plausible on its face under the familiar *Twombly/Iqbal* pleading standard. Rule 8 of the Federal Rules of Civil Procedure requires that the complaint contain a short and plain statement showing that the plaintiff is entitled to relief. In order to overcome a motion to dismiss, plaintiff's complaint must contain sufficient factual content, not mere conclusory allegations, to raise a plausible inference of wrongdoing. *16630 Southfield Limited Partnership v. Flagstar Bank*, 727 F.3d 502, 504 (6th Cir. 2013) (citations omitted). The burden is on the defense to prove that the plaintiff has failed to state a claim for relief. This Court must view the complaint in the light most favorable to the plaintiff and accept all well-pleaded factual allegations as true. *Marcum v. DePuy Orthopedics, Inc.*, 2013 WL 1867010 (S.D. Ohio).

Defendant contends that Plaintiff fails to plead sufficiently and support her six causes of action because she does not identify how the SCS 1132 was allegedly defective or how it supposedly caused her injuries.

For those surviving counts—Counts One, Two, and Four—this Court finds that Plaintiff has sufficiently pled causation.

Count One's allegation of a defective design or manufacture of the medical device at issue is not a formulaic recitation of the law. It is not, as Defendants claim, an "unadorned, the-defendant-unlawfully-harmed-me," accusation. (ECF No. 23). To the contrary, Count One alleges that the Defendant designed, manufacture, and sold an unreasonably dangerous and defective product to Ohio consumers and failed to comply with the PMA specifications, rendering it more dangerous than an ordinary consumer would expect or foresee. Count Two contends that Defendant knew or should have known of the potential for the devices malfunction and, nevertheless, failed to provide adequate warnings both at the time of marketing and afterward. And Count Four claims a violation of warranties regarding the safety and utility of the medical device, bolstered by marketing literature. Counts One, Two, and Four survive.

III. CONCLUSION

For the reasons above, the Court **GRANTS IN PART** and **DENIES IN PART** Defendant's Motion to Dismiss Plaintiff's First Amended Complaint. Defendant's Motion to Dismiss is **GRANTED** as to Counts Three, Five, and Six and **DENIED** as to Counts One, Two, and Four.

IT IS SO ORDERED.

ALGENON L. MARBLEY
CHIEF UNITED STATES DISTRICT JUDGE

DATE: October 14, 2020